PATENT
ATTENTION: MS AFTER FINAL
RESPONSE UNDER 37 C.F.R. § 1.116
EXPEDITED PROCEDURE REQUESTED
EXAMINING GROUP 1600

Confirmation no. 3131
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re reissue application of: U.S. Pat. No. 6,348,481, issued February 19, 2002

Applicants: Yoshiyuki INADA, et al.

Title: PHARMACEUTICAL COMPOSITION FOR ANGIOTENSIN II-MEDIATED DISEASES

Appl. No.: 10/781,263

Filing Date: 02/19/2004

Examiner: Deborah C. Lambkin

Art Unit: 1626

SUPPLEMENTAL DECLARATION FOR REISSUE PATENT APPLICATION TO CORRECT "ERRORS" STATEMENT (37 CFR § 1.175)

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We, Yoshiyuki Inada and Keiji Kubo, hereby declare that:

1. I understand the written English language at least well enough to understand the content of present declaration and the content of any document(s) to which the present declaration relates.

2. Every error in the patent which was corrected in the present reissue application, and which is not covered by the prior oath(s) and/or declaration(s) submitted in this application, arose without any deceptive intention on the part of the applicant.

3. Each inventor's residence, mailing address, and citizenship are as stated below next to his/her name.

4. I believe the inventors named below to be the original and first inventors of the subject matter which is claimed an for which a patent is sought on the invention in the present application no. 10/781,263, entitled:

PHARMACEUTICAL COMPOSITION FOR ANGIOTENSIN II-MEDIATED DISEASES

the claims of which are as follows:

1. A method for the treatment of angiotension II-mediated disease in a mammal in need thereof which comprises administering an effective amount of

(±)-1-(cyclohexyloxycarbonyloxy)ethyl 2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylate,

2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, or

2-ethoxy-1-[[2'-(2,5-dihydro-5-oxo-1,2,4-oxadiazol-3-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, or a pharmaceutically acceptable salt thereof, in combination with an effective amount of furosemide.

2. A method according to claim 1, wherein the disease is hypertension, cardiac insufficiency, ischemic peripheral circulation disturbances, myocardial ischemia, vein insufficiency, progressive cardiac insufficiency after myocardial infarction, diabetic nephritides, nephritis, arteriosclerosis, hyperaldosteronism, dermatosclerosis, glomerulosclerosis, renal insufficiency, diseases of central nervous system, sensory disturbances, deficiency of memory, depression, amnesia and

senile dementia, anxiety neurosis, catatonia, glaucoma, or intraocular high tension.

3. A method according to claim 1, wherein the disease is hypertension.

4. A pharmaceutical composition which comprises at least one of :

(±)-1-(cyclohexyloxycarbonyloxy)ethyl 2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylate,

2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7- carboxylic acid, or

2-ethoxy-1-[[2'-(2,5-dihydro-5-oxo-1,2,4-oxadiazol-3-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, or a pharmaceutically acceptable salt thereof, in combination with a compound having diuretic activity or a compound having calcium antagonistic activity.

5. The composition of claim 4, in which the compound having diuretic activity is a member selected from the group consisting of amiloride, chlorothiazide, hydrochloride, benzthiazide, ticrynafen, acetazolamide, aminophylline, cyclothiazide, cyclopentiazide, methyclothiazide, benthylhydrochlorothiazide, penfluthiazide, ethiazide, hydroflumethiazide, polythiazide, chlophenamide, chlorthalidone, cyclothiazide, bendroflumethiazide, meticrane, tripamide, metrazone, quinethazone, bumetanide, mefruside, azosemide, ethacrynic acid, sodium ethacrynate, piretanide,

spironolactone, potassium canrenoate, quinethazone and triamterene.

6. The composition of claim 4, in which the compound having calcium antagonistic activity is a member selected from the group consisting of diltiazem hydrochloride, teloridine hydrochloride, nicardipine hydrochloride, varnidipine hydrochloride, flunarizine hydrochloride, verapamil hydrochloride, cinnarizine, nisoldipine, nitrendipine, nifedipine, nilvadipine, felodipine, nildipine, nimodipine, penidipine and benidipine.

7. A method for treatment of angiotensin II mediated diseases in a mammal in need thereof which comprises administering an effective amount of at least one of

(±)-1-(cyclohexyloxycarbonyloxy)ethyl 2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylate,

2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7- carboxylic acid, or

2-ethoxy-1-[[2'-(2,5-dihydro-5-oxo-1,2,4-oxadiazol-3-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, or a pharmaceutically acceptable salt thereof, in combination with a compound having diuretic activity or a compound having calcium antagonistic activity.

8. The method of claim 7, in which the angiotensin II-mediated diseases is selected from the group consisting of hypertension, cardiac insufficiency, ischemic peripheral circulation disturbances, myocardial ischemia, vein

insufficiency, progressive cardiac insufficiency after myocardial infarction, diabetic nephritides, nephritis, arteriosclerosis, hyperaldosteronism, dermatosclerosis, glomerulosclerosis, renal insufficiency, diseases of central nervous system, sensory disturbances, deficiency of memory, depression, amnesia and senile dementia, anxiety neurosis, catatonia, glaucoma and intraocular high tension.

9. The method of claim 7, wherein the compound having diuretic activity is a member selected from the group consisting of amiloride, chlorothiazide, hydrochloride, benzthiazide, ticrynafen, acetazolamide, aminophylline, cyclothiazide, trichloromethiazide, cyclopentiazide, hydrochlorothiazide, methyclothiazide, benthylhydrochlorothiazide, penfluthiazide, ethiazide, hydroflumethiazide, polythiazide, chlophenamide, chlorthalidone, cyclothiazide, bendroflumethiazide, meticrane, tripamide, metrazone, indapamide, quinethazone, furosemide, bumetanide, mefruside, azosemide, ethacrynic acid, sodium ethacrynate, piretanide, spironolactone, potassium canrenoate, quinethazone and triamterene.

10. The method of claim 7, wherein the compound having calcium antagonistic activity is a member selected from the group consisting of diltiazem hydrochloride, teloridine hydrochloride, nicardipine hydrochloride, varnidipine hydrochloride, flunarizine hydrochloride, verapamil hydrochloride, manidipine hydrochloride, cinnarizine, nisoldipine, nitrendipine, nifedipine, nilvadipine, felodipine, nildipine, nimodipine, penidipine and benidipine.

5. I hereby declare that the subject matter of the claims was part of the invention and was invented before the filing date of the original application, above identified for such invention.

6. I hereby state that I have reviewed and understand the contents of the above-identified specification (attached herewith), including the claims as shown in amended form above.

7. I acknowledge the duty to disclose information which is material to patentablility as defined in 37 CFR § 1.56, including for continuation-in-in part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

8. I hereby claim foreign priority benefits under 35 USC § 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below:

JP 135524-1993, filed 06/07/1993.

9. The previous paragraph corrects an inadvertent typographical error in the priority claim (~~133524-1993,~~ 135524-1993) made in the original "Broadening Reissue Declaration."

Conclusion

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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